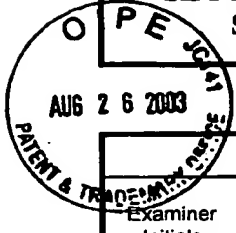


Substitute for forms 1449A/PTO &amp; 1449B/PTO

ATTORNEY'S DKT NO.  
033053-040APPLICATION NO.  
09/974,768SECOND INFORMATION DISCLOSURE  
STATEMENT BY APPLICANTAPPLICANT  
Kenneth C. CUNDY et al.FILING DATE  
October 9, 2001GROUP  
1614
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 AUG 27 2003  
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## U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
BTB	5,695,738		Anderson et al.	12-09-1997
BTB	5,725,840		Klaveness et al.	03-10-1998

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## FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation Yes	No
BTB	JP 11-60954		Japan	03-02-1999	X	

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.

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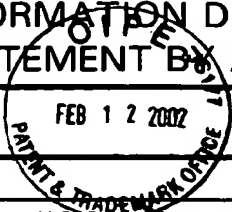
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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	ATTORNEY'S DKT No. 033053-040	APPLICATION No. 09/974,768
	APPLICANT Kenneth C. Cundy, et al.	
	FILING DATE October 9, 2001	GROUP 1614



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U.S. PATENT DOCUMENTS						
Examiner Initials	U.S. Patent Document /		Name of Patentee or Applicant of Cited Document	Date of Publication (MM-DD-YYYY)		
	Number	Kind Code (if known)				
BB	5,352,682		Sipos	10/4/94		
	5,462,933		Kramer et al.	10/31/95		
	5,541,348		Arya et al.	7/30/96		
	5,646,272		Kramer et al.	7/8/97		
	5,668,126		Kramer et al.	9/16/97		
BB	5,942,248		Barnwell	8/24/99		

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Foreign Patent Document		Country	Date of Publication (MM-DD-YYYY)	Translation	
	Number	Kind Code (if known)			Yes	no
BB	0272462B1		Europe	6/29/88		

NON PATENT LITERATURE DOCUMENTS	
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BB	Adibi, S.A., "The oligopeptide transporter (Pept-1) in human intestine: Biology and Function", <i>Gastroenterology</i> , Vol. 113, pp. 332-340, 1997.
	Baringhaus, K.H., et al., "Substrate specificity of the ileal and hepatic Na <sup>+</sup> / bile acid cotransporters of the rabbit. II. A reliable 3D QSAR pharmacophore model for the ileal Na <sup>+</sup> / bile acid cotransporter", <i>J. Lipid Res.</i> , Vol. 40, pp. 2158-2168, 1999.
	Bryans, J. S., et al., "3-Substituted GABA analogs with central nervous system activity: a review", <i>Med. Res. Rev.</i> , Vol. 19, pp. 149-177, 1999
	Bundgaard, H., in <i>Design of Prodrugs</i> (Bundgaard, H. Ed.), Elsevier Science B.V., pp. 1-92, 1985.
	Dieck, S.T., et al., "The peptide transporter PepT2 is expressed in rat brain and mediates the accumulation of the fluorescent dipeptide derivative $\beta$ -Ala-Lys-N <sub>3</sub> -AMCA in astrocytes", <i>GLIA</i> , Vol. 25, pp. 10-20, 1999.
	Ho, N. F. H., "Utilizing bile acid carrier mechanisms to enhance liver and small intestine absorption", <i>Ann. N. Y. Acad. Sci.</i> , Vol. 507, pp. 315-329, 1987.
BB	Jezyk, N., et al., "Transport of Pregabalin in Rat Intestine and Caco-2 Monolayers", <i>Pharm. Res.</i> , Vol. 16, pp. 519-526, 1999

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APPLICATION No.  
09/974.768

APPLICANT  
Kenneth C. Cundy, et al.

**FILING DATE**  
October 9, 2001

**GROUP  
1614**

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Kramer, W, et al., "Liver-specific drug targeting by coupling to bile acids", *J. Biol. Chem.*, Vol. 267, pp. 18598-18604, 1992.

Kramer, W., et al., "Intestinal absorption of peptides by coupling to bile acids", *J. Biol. Chem.*, Vol. 269, pp. 10621-10627, 1994.

Kramer, W., "Bile acid derived HMG-CoA reductase inhibitors", *Biochim. Biophys. Acta.*, Vol. 1227, pp. 137-154, 1994.

Kramer, W., et al., "Substrate specificity of the ileal and hepatic Na<sup>+</sup> / bile acid cotransporters of the rabbit. I. Transport studies with membrane vesicles and cell lines expressing the cloned transporters", *J. Lipid Res.*, Vol. 40, pp. 1604-1617, 1999.

Kullak-Ublick, G.A., et al., "Hepatobiliary transport", *J. Hepatology*, Vol. 32 (Suppl. 1), pp. 3-18, 2000

Leibach, et al., "Peptide transporters in the intestine and the kidney", *Ann. Rev. Nutr.*, Vol.16, pp. 99-119, 1996

Mills, C.O., et al., "Teal absorption of tyrosine-conjugated bile acids in Wistar rats", *Biochim. Biophys. Acta*, Vol. 926, pp. 154-159, 1987.

Navia, M.A., "Design principles for orally bioavailable drugs", *Drug Discovery Today*, Vol. 1, pp. 179-189, 1996.

Petzinger, E., et al., "Hepatobiliary transport of hepatic 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors conjugated with bile acids", *Hepatology*, Vol. 22, pp. 1801-1811, 1995.

Swaan, P.W., *Use of the intestinal and hepatic bile acid transporters for drug delivery*, Adv. Drug Delivery Rev. 1996, 20, pp. 59-82.

Swaan, P.W., et al., "Enhanced transepithelial transport of peptides by conjugation to cholic acid", *Bioconj. Chem.*, Vol. 8, pp. 520-525, 1997.

Tsuji, A., et al., "Carrier-mediated intestinal transport of drugs", *Pharm. Res.*, Vol. 13, pp. 963-977, 1996.

Wong, et al., "Electrophysiological characteristics of the proton-coupled peptide transporter PEPT2 cloned from rat brain", *Am. J. Physiol.*, Vol. 275, pp. C967-C975, 1998.

**Examiner  
Signature**

Date  
Considered

6/16/03